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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,901	08/07/2001	Kanji Takada	P21010	2415

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,901	TAKADA, KANJI	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

As stated in the communication mailed on December 2, 2003, upon review of the application, the Supervisor has determined that a unitary concept for the invention exists and the restriction requirement is withdrawn. Therefore, this supplemental office action is issued to exam all the pending claims on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US 4765983). Takayanagi teaches an adhesive medical tape containing an active agent in an adhesive layer and a support layer (Col. 1, line 55 – Col. 2, line 12). The drug is contained in a water-soluble polymer layer (Col. 2, line 58 – Col. 3, line 5). The medicament layer can be composed of one or more

layers (Col. 3, lines 18-41). The support layer is composed of an *intestine soluble* polymer such as hydroxypropyl methylcellulose phthalate or poly(methacrylic acid, methylmethacrylate) (Col. 3, line 50 – Col. 4, line 4). The support layer thickness is from 2 to 20 microns and the medicament layer thickness is from 20 to 300 microns (Col. 10, Claim 4). The film or tape is delivered to the digestive tract (Col. 1, lines 55-61). Takayanagi does not expressly teach that the adhesive layer is in a hemispherical form with the dimensions recited in instant Claims 4 and 5.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a tape or patch suitable for the digestive tract wherein the device comprises a backing layer that is impermeable to the drug, a drug layer and an adhesive layer. The Examiner does not see the criticality in the particular form of the adhesive layer or the particular dimensions of the form. The prior art teaches a tape or patch that contains the same laminated layers for the same purpose. The art teaches a tape that has a backing layer, drug layer and adhesive layer that attached to a portion of the digestive tract to deliver a drug. The recited dimensions would be routinely determined by one of ordinary skill in the art absent a showing of unusual, superior or unexpected results. The results must be those that accrue from the specific limitations.

One of ordinary skill in the art would have been motivated to do this to provide a device that delivers the drug effectively with minimal side effects over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al. (US 4765983) in combination with Uyama et al. (US 6086869). The teachings of Takayanagi are discussed above. Takayanagi does not expressly teach the active agent to be interferon.

Uyama teaches that interferon can be orally administered in various forms. (Col. 6, Claim 7).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to place an active agent such as interferon in a film composition that is administered in matrix or capsule form.

One of ordinary skill in the art would have been motivated to do this to treat various diseases such as retinal edema in an effective manner over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. (US 4767627) in combination with Takayanagi et al. (US 4765983). Caldwell teaches a planar disc comprising at least one erodible polymer and an active agent (Col. 42-62). This planar disk can be made from erodible polymers or non-erodible polymers (Col. 5, line 46 – Col. 6, line 23). The erodible polymers can be hydroxypropyl methylcellulose phthalate or poly(methacrylic acid) (Col. 5, lines 46-68). The drug can be present in an erodible matrix or non-erodible matrix (Col. 6, lines 24-44). One matrix can be attached to the other for administration of the matrix (Col. 6,

lines 24-44). The matrix is then compressed by folding or rolling and then inserted into a capsule for delivery (Col. 4, lines 22-32). The active agent in not critical and can be any active in it stable form (Col. 6, lines 55-68). The devices of the Caldwell reference (the discs inserted into the capsule) can be manufactured by molding, extrusion, film-forming or laminating (Col. 5, lines 10-17). Caldwell does not specifically teach the multiple layer of a laminate or film composition but generally teaches a device that can be formed from suitable polymers so as to be able to be placed in a capsule and delivered to the digestive tract.

Takayanagi teaches an adhesive medical tape containing an active agent in an adhesive layer and a support layer (Col. 1, line 55 – Col. 2, line 12). The drug is contained in a water-soluble polymer layer (Col. 2, line 58 – Col. 3, line 5). The medicament layer can be composed of one or more layers (Col. 3, lines 18-41). The support layer is composed of an *intestine soluble* polymer such as hydroxypropyl methylcellulose phthalate or poly(methacrylic acid, methylmethacrylate) (Col. 3, line 50 – Col. 4, line 4). The support layer thickness is from 2 to 20 microns and the medicament layer thickness is from 20 to 300 microns (Col. 10, Claim 4). The film or tape is delivered to the digestive tract (Col. 1, lines 55-61). Takayanagi does not expressly teach that the film is contained within a capsule.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a capsule containing a planar disc or patch to be delivered to the digestive tract of an individual or animal wherein the disc or patch can

be formed by film-forming or laminating methods such as the film or patch of Takayanagi.

One of ordinary skill in the art would have been motivated to do this to provide a formulation that can be retained in the stomach for an extended period of time thereby improving bioavailability of the drug (Caldwell, Col. 3, lines 3-11). Both references teach composition that are intended to release the active agent over an extended period of time and are delivered to the digestive tract of the individual or animal. The primary reference teaches a capsule with a film or patch like composition contained within the capsule to be delivered to the digestive tract. The secondary reference shows a type of patch or film that can also be delivered to the digestive tract that further contains polymer that are digestible in the intestines. One would be motivated to be substitute the disc or patch contained within the capsule depending upon the drug used or the period of time the device is to deliver the drug contained within the tape or patch portion of the device. Therefore, it is the position of the Examiner that the composition could further deliver the drug in the stomach over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. (US 4767627) in combination with Takayanagi et al. (US 4765983) in further combination with Uyama et al. (US 6086869). The teachings of Takayanagi and Caldwell are discussed above. Neither Takayanagi not Caldwell teach the active agent to be interferon.

Uyama teaches that interferon can be orally administered in various forms. (Col. 6, Claim 7).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to place an active agent such as interferon in a film composition that is administered in capsule form.

One of ordinary skill in the art would have been motivated to do this to treat various diseases such as retinal edema over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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